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No. 91-674

IN THE

Supreme Court Of The United States

OCTOBER TERM, 1991

Chaves County Home Health Service, Inc., Albuquerque Visiting Nurse Service, Inc., and Bayonne Visiting Nurse Association, Inc.,

Petitioners,

v.

Louis W. Sullivan, M.D.,
Secretary of Health and Human Services,

Respondent.

BRIEF OF AMICI CURIAE IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMICI CURIAE:
National Association of Rehabilitation Agencies
American Physical Therapy Association
American Occupational Therapy Association
American Medical Association
American Speech-Language Hearing Association
Private Practice Section of the American Physical Therapy Association

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This brief *amici curiae* in support of the Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit is submitted by the National Association of Rehabilitation Agencies ("NARA"), American Physical Therapy Association ("APTA"), American Occupational Therapy Association ("AOTA"), American Medical Association ("AMA"), American Speech-Language Hearing Association ("ASHA"), and the Private Practice Section of the American Physical Therapy Association ("PPS")(hereinafter collectively "*Amici*"). For the reasons set out herein, in the Petition for Writ of Certiorari, as well as in the Brief of *Amici Curiae* submitted by the American Hospital Association, American Association of Homes for the Aging, American Federation of Home Health Agencies, and the Home Health Services and Staffing Association, these *Amici* respectfully

request this Court to grant the petition for a writ of certiorari so that the lawfulness of the Secretary of Health and Human Services' ("Secretary") sample adjudication scheme may be reviewed.

I. INTEREST OF AMICI CURIAE

The *Amici* are six national professional associations representing tens of thousands of health care providers which furnish medical services to millions of Medicare beneficiaries.[1] Members of these organizations are "providers" or "suppliers" of services under the Medicare program (42 U.S.C. § 1395x(u)) whose services are paid for principally under Part B of Medicare, although members of these associations render some services which may be covered by Part A. The *Amici* are convinced that the Secretary's use of sample adjudication will cause serious harm to Part B providers, beneficiaries of Part B care, and the Medicare program itself.

NARA, a not-for-profit corporation organized under the laws of the State of Wisconsin, represents approximately 200 Medicare-certified rehabilitation agencies nationwide. Rehabilitation agencies provide their patients with integrated multi-disciplinary rehabilitative services including physical therapy, speech-language pathology, occupational therapy, and social or vocational adjustment services. Many of the services furnished by rehabilitation agencies are rendered to Medicare beneficiaries for which payment is made by the Medicare program.

APTA, an Illinois corporation, is a non-profit association composed of licensed physical therapists, physical therapist assistants, and students of physical therapy. APTA has over 51,000 members and represents approximately 60% of all licensed physical therapists in the United States. As such, APTA is the largest organization of these health professionals

[1] The consents of all the parties to the filing of this brief have been filed with the Court.

in the country and is the recognized spokesman for their interests. Medicare beneficiaries are frequent users of services furnished by members of APTA and Medicare covers the costs of such care.

ASHA is a Kansas non-profit corporation which represents approximately 75% of the speech-language pathologists and audiologists in the country. With over 65,000 members, ASHA is the nationally-recognized advocate for the interests of these professionals. Speech-language pathology and audiology services furnished to Medicare beneficiaries are covered and paid for by Medicare.

AOTA is a District of Columbia non-profit corporation which represents the professional interests of over 44,000 occupational therapists, occupational therapist assistants, and students of occupational therapy. Occupational therapy services are covered under the Medicare program and AOTA members provide services to program beneficiaries in a variety of delivery settings.

AMA is a private, voluntary, non-profit organization of physicians. The AMA was founded in 1846 to promote the science and the art of medicine and improve the public health. Its 280,000 members – over half of all physicians currently licensed to practice medicine – practice in all fields of medical specialization.

PPS, organized in 1956, represents over 5,000 physical therapists who pursue their profession in private practice instead of in hospitals, rehabilitation centers, nursing homes, or similar institutional settings. The PPS also represents physical therapy students, educators, researchers, physical therapist assistants, and administrative assistants. PPS represents private practice physical therapists before governmental agencies, professional and voluntary associations, and numerous public forums.

The *Amici* vigorously support the petition for a writ of certiorari because the Secretary's use of statistical sampling methodologies to adjudicate Medicare claims will carry the following dire consequences:

First, sampling will likely cause severe financial hardship to, and perhaps the insolvency of, any provider against whom the technique is used. The pernicious consequences of statistical sampling are evident from the undisputed facts in the case before the Court. On the basis of extremely small samples of claims, the Secretary demanded repayment of $138,113.38 from Albuquerque Visiting Nurse Service, Inc., $46,913.19 from Chaves County Home Health Service, Inc., and $1,506,639.00 from Bayonne Visiting Nurse Association, Inc. The Secretary's repayment demands forced Albuquerque VNS into bankruptcy and nearly led to the insolvency of Bayonne VNA as well. In another case, a Medicare-certified rehabilitation agency was forced to close its doors as a result of the Secretary's use of statistical sampling. *See Mile High Physical Therapy Centers, Inc. v. Bowen*, 735 F. Supp. 984 (D. Colo. 1988).

The *Amici* respectfully submit that if the use of statistical sampling is upheld, the financial demise of numerous Medicare Part B (and Part A) providers and suppliers will be ordained.

Second, at a time when the aged population is expanding rapidly and the demand for Medicare services is growing at an unprecedented rate, statistical sampling will deter providers from participating in the Medicare program and impair the ability of existing providers to furnish services to Medicare beneficiaries. Statistical sampling significantly increases the business risk associated with entering into a provider participation agreement with the Secretary because even small, good faith errors on claims submitted for payment can result in huge repayment demands. The risk, of course, is heightened as Medicare carriers and intermediaries become more scrupulous

in their claims review in the face of mounting budget deficit pressures to reduce Medicare program costs.

Third, as explained more fully below, statistical sampling deprives providers and beneficiaries of their rights to individualized claims review. *See infra* at 13-15. The absence of individual determinations harms providers because they have no opportunity to defend themselves through the use of medical records and expert testimony on claims not included in the sample. In addition, individual claims determinations furnish providers with a constant source of information about subtle, yet important, shifts in the types of claims which intermediaries and carriers will pay as well as the documentation they require to support payment of a claim. Statistical sampling subverts this dialogue and makes it far more difficult for providers to respond in a timely fashion to changes in a carrier or fiscal intermediary's coverage interpretations or documentation requirements.

Fourth, faced with the prospect of an enormous repayment demand resulting from statistical sampling, providers will refrain from providing care or entering into a course of treatment with a patient where there is even the slightest question whether Medicare will cover it. Sampling, therefore, forces providers to alter their methods of practice and treatment patterns even for services which are legitimate and needed by the beneficiary. As a result, Medicare beneficiaries will have significantly reduced access to health care services which they require.

Fifth, sampling prevents providers from collecting payments due from beneficiaries for services not covered by Medicare. *See infra* at 15. Under the law, providers have the right to collect payment from beneficiaries where Medicare has declined to pay for the service. Fundamental to a provider's ability to collect such payment is the identification of the beneficiary whose claim was denied as well as the reasons for the denial. Because, by definition, sampling does not identify the beneficiary or the reasons for the denial for any claim not

included in the sample – *i.e.*, the majority of denied claims – the provider has no way of exercising its right of recourse against the beneficiary. Sampling, therefore, is a "double-whammy" for providers. On one hand, it inevitably results in huge repayment demands. On the other, it precludes providers from offsetting those losses by collecting funds lawfully due them from beneficiaries.

II. SUMMARY OF ARGUMENT

The *Amici* urge this Court to grant the petition for writ of certiorari and ultimately hold that the use of statistical sampling to readjudicate Medicare coverage determinations is unlawful. Sample adjudication causes grievous financial injury to Medicare providers, deters them from providing needed care to Medicare beneficiaries, and precludes providers from collecting payments due from beneficiaries for services which Medicare has determined that it will not cover.

The Court should review the Court of Appeals' decision because it directly contravenes specific statutory and regulatory mandates under Part B and Part A of Medicare for individualized claims review, notice of the reasons for coverage denials, the right to appeal adverse determinations, payment under waiver of liability, and recourse against beneficiaries for unpaid claims. Furthermore, the decision below flies in the face of long-standing decisions by this Court which mandate specific procedural protections for Medicare providers. The Court of Appeals' decision also conflicts with the rulemaking requirements of the Administrative Procedure Act as articulated by this Court.

III. STATEMENT OF THE CASE

A. Part B of the Medicare Program

Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, commonly known as "Medicare", consists of two parts. Part A provides insurance protection against the costs of inpatient hospital and related post-hospital services, home health

care, and hospice care for individuals who are 65 or over or who are otherwise entitled to Medicare benefits. 42 U.S.C. §§ 1395c - 1395i - 4. Part B of the Medicare program is entitled "Supplementary Medical Insurance Benefits for the Aged and Disabled." It furnishes insurance coverage for a broad spectrum of health and medical services including, *inter alia*: certain physicians services and supplies and services incident to physicians' services; physical therapy, speech pathology, and occupational therapy services; outpatient hospital services; rural and community health clinic services; ambulatory surgery; care provided by comprehensive outpatient rehabilitation facilities; and x-ray, laboratory, and other diagnostic tests. 42 U.S.C. §§ 1395k - 1395x(nn).

Medicare Part B is a substantial federal program. Approximately 32.6 million individuals currently participate in the Medicare supplementary insurance program and in excess of $42 billion in Part B benefits are paid out annually. Physical therapists, speech pathologists, occupational therapists, physicians and other health professionals represented by the *Amici* herein submit millions of Part B claims annually.

Part B is administered by the Secretary who is authorized by statute to contract with private insurance carriers to review and pay, on the Secretary's behalf, all Part B claims.[2] 42 U.S.C. § 1395u. These carriers act as the Secretary's agents for this purpose (42 C.F.R. § 421.5) and the Secretary pays the carriers' costs of administering the Part B claims process. 42 U.S.C. § 1395u(c).

B. Part B Claims Review and Adjudication

Medicare carriers review, adjudicate, and pay Part B claims pursuant to procedures precisely specified in the Medicare statute and the Secretary's regulations. The procedures, which guarantee providers the right to individualized factual deter-

[2] Under certain circumstances, some Part B providers have their claims reviewed and paid by fiscal intermediaries rather than carriers.

minations, notice, and appeal, find their genesis in the claims adjudication process formulated over 45 years ago for Title II of the Social Security Act. *See* 42 U.S.C. § 405(a),(b),(g) as incorporated by 42 U.S.C. §§ 1395ff, 1395ii. These procedures were adopted for Medicare beneficiaries for Part A coverage determinations in 1965. Pub. L. No. 89-97, § 102, 79 Stat. 286 (1965), (codified at 42 U.S.C. § 1395ff(b)). *See also* 42 C.F.R. § 405.701. They were put in place for providers of services under Part A in 1972. Pub. L. No. 92-603, § 213(a)(1972) (codified at 42 U.S.C. § 1395pp(d)). While Part B providers had access to the initial determination, notice, and fair hearing procedures prior to 1986, the opportunity for administrative law judge hearings and judicial review of Part B claims was not extended until 1986. Pub. L. No. 99-509, § 9341(a) (1)(A-D), 100 Stat. 1874 (1986) (codified at 42 U.S.C. § 1395ff(a),(b).

The statutory basis for Part B provider rights to individual factual determinations and administrative and judicial review resides in 42 U.S.C. § 1395ff which states in pertinent part: "The determination of whether an individual is entitled to benefits under Part A or Part B..., and the determination of the amount of benefits under Part A or Part B..., shall be made by the Secretary in accordance with regulations prescribed by him."

When a beneficiary or provider of services submits a claim for payment, the carrier makes an initial determination whether it should be paid. 42 C.F.R. § 405.803. The initial determination involves deciding whether the services were covered by Medicare; whether the services were medically necessary; whether the charges for services were reasonable; and whether the beneficiary or provider "knew or could reasonably have been expected to know that such items or services were excluded from coverage." 42 C.F.R. § 405.803(b). The very nature of these determinations demand a highly individualized analysis of the facts concerning the beneficiary and the claim.

A party dissatisfied with the initial decision may request the carrier to review the determination. 42 C.F.R. § 405.807. The carrier reviews the claim on the basis of the evidence in the record and issues a separate determination affirming, reversing, or revising the initial determination. 42 C.F.R. § 405.810.

A party has the right to a hearing before a carrier hearing officer if the carrier's decision on review is not favorable and the amount in controversy is at least $100.00. 42 C.F.R. § 405.820. The hearing is on the record (42 C.F.R. § 405.833) and the provider of services or the beneficiary may appear at the hearing and present testimony and other evidence. 42 C.F.R. § 405.830. The hearing officer must make a written decision based upon the evidence in the hearing record. 42 C.F.R. § 405.834. The decision is final and binding on all parties (42 C.F.R. § 405.840) unless it is reopened and revised pursuant to 42 C.F.R. § 405.841.

A claim dispute may be appealed to an administrative law judge ("ALJ") provided that the amount in controversy exceeds $500. 42 U.S.C. § 1395ff. At an ALJ hearing, a party is entitled to present its case through documentary evidence and witnesses. 20 C.F.R. § 404.950. A transcript of the testimony and exhibits, together with all other papers submitted in the case, forms the exclusive record upon which the ALJ's decision must be based. 20 C.F.R. § 404.951.

An adverse decision by an ALJ may be appealed to the Appeals Council (20 C.F.R. § 404.967) or, alternatively, the Appeals Council itself may decide to review the decision. 20 C.F.R. § 404.969. Appeals Council review is predicated on the record before the ALJ as well as any new evidence accepted by the Council. 20 C.F.R. § 404.976(b). The Appeals Council has the authority to render a final decision on behalf of the Secretary which is then subject to judicial review. 20 C.F.R. § 404.981. If the Appeals Council declines to take review, the ALJ decision

becomes the final decision of the Secretary and is subject to judicial review. 20 C.F.R. § 404.981.

42 U.S.C. § 1395ff provides for judicial review of Medicare Part B claims where the amount in controversy is at least $1,000. 42 U.S C. § 1395ff(b)(2)(B).

C. The Secretary's Use of Sample Adjudication

In this case, the Secretary abrogated the rights of three home health agencies to individualized factual determinations, notice and appeal under Part A by utilizing a sampling procedure to readjudicate and deny thousands of claims that had previously been determined to be covered pursuant to the Secretary's claims review procedures. The Secretary's sampling procedure operated as follows: he conducted a post-payment review of a small sample of each provider's claims and then extrapolated the percentage of newly denied claims to the remaining universe of unreviewed claims. This methodology resulted in the readjudication of the claims not included in the sample without affording the providers the procedural rights to which they were entitled. The Secretary did not even identify the specific claims in the universe which were disallowed.

Although this case involves only Part A of Medicare, its disposition will have an identical impact on Part B providers such as those represented by the *Amici*. Indeed, the Secretary has in the past employed statistical sampling against Part B providers. *See Mile High Therapy Centers, Inc. v. Bowen*, 735 F. Supp. 984 (D. Colo. 1988). The Court of Appeals below recognized that the decision in *Chaves* would govern Part B providers:

> Although Part B is somewhat different from Part A, there is no essential difference in their recoupment powers for coverage overpayments. Furthermore, amendments added in 1986 extended Part A claims adjudication procedures to Part B claims as well.

> (Consequently, a contrary holding on the statutory question in this case could imperil sample adjudication under Part B).

Chaves County Home Health Service v. Sullivan, 931 F.2d 914, 918-19 (D.C. Cir. 1991).

D. The Decisions Below

The Court of Appeals rendered its decision in this case on April 26, 1991. The court held that: (1) sampling procedures for recoupment of overpayments to home health care providers do not violate the Medicare statute; (2) sample adjudication does not violate procedural due process; and (3) the sample audit procedures were not impermissibly retroactive and were not in violation of Administrative Procedure Act requirements. *Chaves*, 931 F.2d at 914.

The court's opinion observed that the question whether sample adjudication is an unreasonable interpretation of the Medicare statute is "close." *Chaves*, 931 F.2d at 923. The Court of Appeals also agreed with the following contentions advanced by the providers: (1) the language and overall structure of the Medicare statute and regulations require individualized factual determinations (*Chaves*, 931 F.2d at 917, 919-20 and 922-23); (2) Medicare providers have the same right to individualized factual determinations as beneficiaries (*Chaves*, 931 F.2d at 917, 919 and 921); and (3) there is no authority in the statute, its legislative history, or in the Secretary's regulations to support the use of sample adjudication. *Chaves*, 931 F.2d at 916 and 922.

Having recognized these principles, however, the court misapplied them. First, the court found that although the statute provides for individualized factual determinations, it does so only for "pre-payment review" and not "post-payment review." Accordingly, the court reasoned, sample adjudication does not conflict with the statutory mandate for individualized claims

review. *Chaves*, 931 F.2d at 917, 921. Although it conceded that neither the statute, its legislative history, nor the regulations provide a basis for differentiating between the adjudication of pre-payment and post-payment claims, the court insisted, absent an explicit prohibition of sampling, that it must defer to the Secretary's general authority to recoup overpayments.

The court also ruled that the different standard of individualized review for post-payment claims met the Medicare statute's requirements for individualized adjudication of claims because it gives claimants the opportunity to challenge the denials of specific claims within the sample. *Chaves,* 931 F.2d at 922-23.

The providers in *Chaves* had asserted that HCFA Ruling 86-1, the ruling which sets out HCFA's procedures for administering sample adjudication, was invalid because it was not promulgated pursuant to the Administrative Procedure Act, 5 U.S.C. § 553 *et seq.* ("APA") and was impermissibly retroactive. The court rejected these arguments finding that the ruling was merely an explanation of a "long-standing and well-established" practice, not an announcement of a new scheme which would require prospective application or compliance with the APA notice and comment requirements. *Chaves*, 931 F.2d at 923.

IV. REASONS FOR GRANTING THE WRIT

A. Statistical Sampling Abrogates Rights Granted to Providers By Statute and Regulation

As explained in detail above, *supra* at 7-10, the Social Security Act and the Secretary's regulations thereunder guarantee Part B providers the absolute right to a comprehensive multi-step administrative process for the review and adjudication of Medicare claims: (1) an initial determination on each beneficiary's claim; (2) carrier review of an adverse initial

decision; (3) a carrier fair hearing in the event the review decision is unfavorable on claims in excess of $100; (4) an appeal to an ALJ if the amount in controversy exceeds $500; and (5) review of the ALJ decision by the Appeals Council. Judicial review of Part B cases is available if the amount in controversy is at least $1,000. These procedural rights exist for every Part B claim.

This procedural scheme is triggered by a single event – the denial of a Medicare Part B claim. For this reason, each step of the process necessarily entails an assessment of highly individualized facts – *e.g.*, whether the services in question were medically necessary given the beneficiary's medical condition, the nature and number of treatments received, the likelihood that the services will improve the patient's condition, pre-existing diseases or injuries, and the effectiveness of the provider's services, etc. Similarly, numerous facts specific to the beneficiary and provider must be examined in determining whether the cost of the service was reasonable.

Sample adjudication operates in fundamental conflict with the principles of individualized review which are clearly articulated in the statute and implementing regulations. As a practical matter, statistical sampling completely circumvents the comprehensive Part B claims review process described above. *See supra* at 6-10.

Except for the claims in the sample, there is no individualized review of any other claim in the universe of claims which will be used to calculate the Medicare overpayment amount. By the very nature of statistical sampling, a Part B provider is accorded all of its procedural rights in only a relatively small portion of its cases. For example, if the Secretary took a sample of 350 claims from 10,000 claims that the provider submitted in a given year and then used the percentage denial rate for the sample to calculate a recoupment amount for the entire universe, the provider would have been deprived of its right to individual-

ized factual determinations, notice, and appeal for 9,650 of its claims. Neither the Social Security Act nor the Secretary's regulations specify that these provider rights need only be afforded in some of the provider's claims cases.

The Court of Appeals attempted to rationalize the deprivation of procedural rights inherent in sample adjudication by asserting that there was a difference in the procedural rights which attach to pre-payment claims review and those which govern post-payment review.

> HHS has not, in fact, suspended individualized determinations and substituted sample adjudication review of payment claims (*a decision that would be inconsistent with the statute*); instead, the Department has supplemented individualized pre-payment review of claims with a sampling procedure on post-payment review of providers suspected of overbilling.

Chaves, 931 F.2d at 917. Emphasis supplied.

The court's argument is specious for several reasons. First, neither the statute nor the Secretary's regulations expressly or implicitly differentiate between the Part B provider rights available on pre- and post-payment review. Quite to the contrary, the statute and regulations clearly afford a provider the full panoply of procedural protections regardless of when the review occurs. Second, the court's argument conveniently ignores the practical effect of sample adjudication. When sampling is used on post-payment review, all of the initial favorable determinations for each of the claims in the universe made on pre-payment review are voided. In a very real sense, therefore, sample adjudication renders the pre-payment protections irrelevant and sampling becomes the only mechanism by which denied claims are adjudicated. Third, if the Court of Appeals is correct in its finding that Part B providers enjoy little protection on post-payment review, the Secretary might well refrain from denying claims on pre-payment review – when providers may exercise

all of their procedural rights — and instead deny the claims on post-payment review where the court below says providers have far more limited rights.

Sample adjudication deprives Part B providers of another crucial right — the right to receive payment for their services. In the event that Medicare denies payment for a claim on the ground that the service was not medically necessary, the provider has the legal authority to seek payment from the patient pursuant to state law. This right has long been recognized by the Secretary[3], Congress[4], and the courts.[5] Statistical sampling renders these rights unenforceable, however, because the provider has no way of identifying the individuals in the universe of unsampled claims whose claims have been denied.

Statistical sampling also disregards the Secretary's duty to furnish detailed reasons for denial whenever a claim is not paid. This information is provided so that the claimant can make a reasonable decision as to whether to pursue administrative or judicial review. Such information is non-existent where sampling is used and so, therefore, is any record upon which an appeal can be predicated. More importantly, this individualized decision-making furnishes beneficiaries and providers with guidance as to those services which will be paid and those which Medicare will not cover. In this way, providers and beneficiaries can avoid submitting claims for which payment is unavailable from Medicare.

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[3] HCFA Ruling 83-1 (1982).

[4] S. Rep. No. 1230, 92d Cong., 2d Sess. 294 (1972).

[5] *Highland District Hospital v. Secretary of HHS*, 676 F.2d 230, 238 (6th Cir. 1982).

B. The Decision of the Court of Appeals Contravenes Long-Standing Holdings By this Court.

The formal Medicare claims adjudication process available to Part B providers arises out of, and is substantially similar to, the claims adjudication process extant in Title II of the Social Security Act as early as 1947. *See* discussion *supra* at 6. This Court, on numerous occasions, has ruled that Title II requires individualized factual determinations, notice of those determinations, and administrative and judicial review. *See e.g.*, *Sullivan v. Zebley*, 493 U.S. 521, 110 S. Ct. 885, 888 and 890 (1990); *Heckler v. Campbell*, 461 U.S. 458, 468 (1983); *Richardson v. Perales*, 402 U.S. 389, 394-98 (1971); and *Bowen v. Yuckert*, 482 U.S. 137 (1987). *Zebley* is particularly instructive in this regard because it states that the Social Security Act's claims adjudication process clearly contemplates individualized functional assessments, because only such review can address the:

> infinite variety of medical conditions and combinations thereof, the varying impact of such conditions due to the claimant's individual characteristics, and the constant evolution of medical diagnostic techniques.

Zebley, 110 S. Ct. at 896.

The progeny of the Title II claims adjudication process — the Medicare Part A and Part B procedures — demand the same review of individualized facts throughout the review process, running from initial determination through judicial review. As explained above, *supra* at 8-9, Medicare Part B claims adjudications necessarily entail highly unique and specific facts for each beneficiary including, *inter alia*, the person's medical condition, medical history, course of treatment, prognosis, etc. Therefore, the Court of Appeals, in ruling that the Secretary may circumvent the multi-step review process for Part B claims, renounced

over two decades of decisions by this Court holding that individualized factual determinations, notice, and administrative and judicial review must be provided under Title II of the Social Security Act.

C. The Decision of the Court of Appeals Conflicts With the Rulemaking Requirements of the Administrative Procedure Act as Articulated by this Court.

In its decision, the Court of Appeals found that sample adjudication was a "long-standing practice" of the Secretary and not "a brand new scheme ushered in by HCFA Ruling 86-1." *Chaves*, 931 F.2d at 923. For this reason, the court ruled that HCFA Ruling 86-1 was an interpretive rule which did not have to be promulgated pursuant to the requirements of the APA. This decision is erroneous and squarely conflicts with the APA's requirements as recognized by this Court.

This Court has carefully delineated the standards which are to be utilized to determine whether an agency rule is "substantive" or "interpretive." A substantive rule is one that is "binding" or has the "force of law" and which "affects individual rights and obligations." *Chrysler Corp. v. Brown*, 441 U.S. 281, 99 S.Ct. 1705, 1717-1718 (1979). *See also Morton v. Ruiz*, 415 U.S. 199, 94 S. Ct. 1055, 1074 (1974). An interpretive rule, by contrast, is not binding, has no future effect, and is merely a statement of what the statute or regulation has always meant in the opinion of the agency issuing the interpretation. *First State Bank of Hudson County v. United States*, 599 F.2d 558 (3rd Cir. 1979), *cert. denied* 444 U.S. 1013 (1980).

Under these standards, HCFA Ruling 86-1 is clearly a substantive rule which should have been promulgated pursuant to the APA. The ruling affects providers rights by depriving them of the comprehensive multi-step administrative procedure for Medicare claims review. It is also binding on the parties because it is used to deny claims on post-payment review which

had been approved for payment on pre-payment review. Furthermore, since the statute and regulations contain no authority for the use of sampling, it stretches credulity to argue that HCFA Ruling 86-1 only restates what the law already provides.

A substantive rule which must be promulgated pursuant to the APA can also arise out of an agency's change in administrative adjudication procedures. In *National Motor Freight Traffic Ass'n v. United States*, 268 F. Supp. 90 (D.D.C. 1967), *aff'd*, 393 U.S. 18 (1968), this Court affirmed a decision which held that an agency rule establishing a scheme for administrative adjudication constituted a substantive rule subject to the APA's notice and comment procedures. The district court had reviewed a series of Interstate Commerce Commission rules which established informal adjudication procedures for carrier overcharge claims. Rejecting the argument that the rules merely established procedures for implementing substantive statutory rights, the court of appeals held that the agency's decision to establish procedures for administrative adjudication was the type of ruling that the APA required to be open to public participation. *National Motor Freight*, 268 F. Supp. at 95-96; *see also* 1 K. Davis, Administrative Law Treatise § 6.29 (2d ed. 1978) (describing *National Motor Freight* as "the most authoritative decision" on the scope of 5 U.S.C. 553(b)(A)).

National Motor Freight is particularly instructive in this case because sample adjudication suspends or circumvents the comprehensive individualized claims review procedures mandated by the Medicare statute and the Secretary's regulations. In so doing, statistical sampling, as provided for in HCFA Ruling 86-1 radically alters the administrative adjudication procedures for Medicare claims. *National Motor Freight* teaches that any such change must be published pursuant to the APA.

The Court of Appeals' only rationale for labeling HCFA Ruling 86-1 an interpretive rule was that sample adjudication was a "long-standing practice" of the Secretary. This finding is

erroneous. Sample adjudication is neither a common nor long-standing practice in Medicare claims cases. Prior to *Chaves*, there is no reported instance of the Secretary's use of sampling to suspend a provider's procedural rights to individual factual determinations, notice, and appeal in Part A cases. Furthermore, the court could point to only one case, *Mile High Therapy Centers*, in which sample adjudication supplanted Part B claims review procedures. This case is inapposite, however, because it involved a sampling methodology utilized by the Secretary prior to the time when the ALJ and judicial review provisions for Part A were extended to Part B providers. Simply put, there was no evidence before the court below that sample adjudication is a long-standing practice.

HCFA Ruling 86-1 is clearly not an interpretive rule. "Interpretive rules are those which merely clarify or explain existing law or regulations." *Powderly v. Schweiker*, 704 F.2d 1092, 1098 (9th Cir. 1983). They are non-binding and do not "foreclose alternative courses of action or conclusively affect rights of private parties." *Batterton v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980). The use of statistical sampling interferes with and suspends the provider's rights to initial determinations, notice, appeal, and waiver of liability under the Medicare Act and regulations. For this reason, HCFA Ruling 86-1 did not merely explain existing law; it created new law which foreclosed providers' administrative procedure rights and in so doing conclusively affected their rights.

A substantive rule is invalid if it is not promulgated pursuant to the procedural requirements of the APA. *Buschmann v. Schweicker*, 676 F.2d 352 (9th Cir. 1982). *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979); *Linoz v. Heckler*, 800 F.2d 871, 878 (9th Cir. 1986); *In re Home Health Care, Inc. v. Bowen*, 639 F. Supp. 1124 (D.D.C. 1986). Because the Secretary failed to comply with the APA requirements in promulgating HCFA Ruling 86-1, that ruling is invalid and cannot provide authority

for the use of sampling methodologies in Medicare overpayment cases. The Court of Appeals' finding to the contrary is in error.

V. CONCLUSION

For all of the reasons set out above, this Court should grant the Petition for a Writ of Certiorari.

Respectfully submitted,

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